

Appl. No. 09/993,300 Amdt. dated Reply to Office action of June 14, 2005

REMARKS/ARGUMENTS

In response to the Office Action of June 14, 2005, Applicants request re-examination and reconsideration of this application for patent pursuant to 35 U.S.C.

Claim Status/Support for Amendments

Claims 1, 39 and 44 have been amended. Claims 2-38 were cancelled in a previous response (filed on March 31, 2005). Claims 39-46 are withdrawn from consideration. It is understood that claims 39-46, drawn to the non-elected invention, will remain pending, albeit withdrawn from consideration on the merits at this time. If the examined claim of the Group I invention is deemed to be allowable, rejoinder of the remaining claims (39-46) in accordance with the decision in *In re Ochiai* is respectfully requested; since the remaining claims (39-46) are limited to the use of the biopolymer markers of claim 1 (the examined claim of the elected Group I invention).

Claim 1 is currently under examination. Claims 1 and 39-46 remain pending in the instant application.

No new matter has been added by the amendments to the claims made herein.

Claims 1, 39 and 44 were amended to recite the proper

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alternative expression and transition phrases to clearly indicate the intended scope of the claims.

Claims 39 and 44 were amended to delete the term "isolated".

Request for Rejoining of Claims

Considering that claims 39-46 are limited to the use of SEQ ID NO:1 and SEQ ID NO:2 a search of these claims would encompass these specific sequences. The instant application is related in claim format to several other applications, both pending and issued, of which serial number 09/846,352 is exemplary. In an effort to maintain equivalent scope in all of these applications, Applicants respectfully request that the Examiner consider rejoining claims 39-46 in the instant application, which are currently drawn to non-elected Groups, with claim 1 of the elected Group under the decision in *In re Ochiai* (MPEP 2116.01), upon the Examiner's determination that claim 1 of the elected invention is allowable and in light of the overlapping search. If the biopolymer markers of SEQ ID NO:1 and SEQ ID NO:2 are found to be novel, methods and kits limited to their use should also be found novel.

Interview with the Examiner

Applicants thank the Examiner for courtesies extended during her telephone interview with Applicants' representatives, Ferris

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Lander and Katharine Davis, on September 15, 2005.

The use of Markush language (alternative expression) and transitional phrases to delineate the scope of the claims was discussed. Both the Examiner and Applicants' representatives agreed that the amendments to the claims as presented herein are sufficient to overcome the rejection under 35 USC 112, second paragraph.

Rejection under 35 USC 112, second paragraph

Claim 1, as presented on March 31, 2005, stands rejected under 35 USC 112, second paragraph as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner asserts that claim 1 does not include a proper transition phrase "comprising" or "consisting of" in the claim. The claim is in the proper Markush Format reciting-selected from the group consisting of. However, while this language provides closed interpretation between SEQ ID NO:1 and SEQ ID NO:2, it does not clearly identify Applicants' intended scope for SEQ ID NO:1 and SEQ ID NO:2.

The "alternative expression" language of claim 1 has been amended herein, the Markush format has been replaced by "or" terminology (see MPEP 2173.05 (h) I, II). Claim 1 has also been

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amended to include the transition phrase "consisting of". The phrase "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03). Since claim 1 now recites an isolated biopolymer marker consisting of SEQ ID NO:1 or consisting of SEQ ID NO:2, the scope is clearly delineated as limited to these specific peptides (SEQ ID NO:1 and SEQ ID NO:2) as disclosed in the instant specification as originally filed at page 46, thus excluding any additional amino acid residues or other elements.

Accordingly, Applicants have now clarified the metes and bounds of the claims and respectfully request that the above-rejection under 35 USC 112, second paragraph be withdrawn.

Rejections under 35 USC 102

Claim 1, as presented on March 31, 2005, remains rejected under 35 USC 102(b) as allegedly being anticipated by Wilson et al. (Science 282:2012-2018 1998).

The Examiner states that Wilson discloses sequences comprising or having SEQ ID NO:2. See GenCore protein search dated 8/3/04. Although the reference is silent with respect to the marker indicating a particular disease state like Alzheimer's disease, this is deemed inherent to the biopolymer. In other words, the sequences set forth in the claim would inherently be markers for

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the claimed diseases. Applicants SEQ ID NO:2 is disclosed as sequence identification number 5 (Q9N3X8) in the reference to Wilson. The Examiner alleges that therein the claimed sequence is taught.

The disclosure of Wilson et al. encompasses the entire genomic sequence of the nematode *Caenorhabditis elegans*. The claimed biopolymer marker SEQ ID NO:2 is a part of this entire sequence.

Claim 1, as instantly presented, recites specific markers (SEQ ID NOS:1 and 2). Furthermore, since "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03), the scope of the instant claim now encompasses only these two specific peptides (SEQ ID NOS:1 and 2) thus excluding the disclosure of Wilson et al. Nowhere does Wilson et al. specifically teach the claimed biopolymer marker sequence (SEQ ID NO:2). Nor does Wilson et al. teach any peptide which is indicative of a link to Type II diabetes.

Accordingly, Applicants respectfully submit that the claim, as instantly presented, now distinguishes over the sequences taught by Wilson et al. and respectfully request that this rejection under 35 USC 102(b) be withdrawn.

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Claim 1, as presented on March 31, 2005, remains rejected under 35 USC 102(a) as allegedly being anticipated by Finan et al. (Proceedings of the National Academy of Science USA 98(17):9889-9894 2001).

The Examiner states that Finan et al. disclose sequences comprising or having SEQ ID NO:1. See GenCore protein search dated 8/3/04. Although the reference is silent with respect to the marker indicating a particular disease state like Alzheimer's disease, this is deemed inherent to the biopolymer. In other words, the sequences set forth in the claim would inherently be markers for the claimed diseases. Applicants SEQ ID NO:1 is disclosed as sequence identification number 2 (C95985) in the reference to Finan et al. The Examiner alleges that therein the claimed sequence is taught.

The disclosure of Finan et al. encompasses the entire genomic sequence of the 1,683-kb pSymB megaplasmid of *Sinorhizobium meliloti*. The claimed biopolymer marker SEQ ID NO:1 is a part of this entire sequence.

Claim 1, as instantly presented, recites specific markers (SEQ ID NOS:1 and 2). Furthermore, since "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03), the scope of the instant claim now encompasses only these two specific peptides (SEQ ID NOS:1 and 2)

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thus excluding the disclosure of Finan et al. Nowhere does Finan et al. specifically teach the claimed biopolymer marker sequence (SEQ ID NO:1). Nor does Finan et al. teach any peptide which is indicative of a link to Type II diabetes.

Accordingly, Applicants respectfully submit that the claim, as instantly presented, now distinguishes over the sequences taught by Finan et al. and respectfully request that this rejection under 35 USC 102(a) be withdrawn.

Claim 1, as presented on March 31, 2005, remains rejected under 35 USC 102(a) as allegedly being anticipated by Galibert et al. (Science 293(5530):668-672 2001).

The Examiner states that Galibert et al. disclose sequences comprising or having SEQ ID NO:1. See GenCore protein search dated 8/3/04. Although the reference is silent with respect to the marker indicating a particular disease state like Alzheimer's disease, this is deemed inherent to the biopolymer. In other words, the sequences set forth in the claim would inherently be markers for the claimed diseases. Applicants SEQ ID NO:1 is disclosed as sequence identification number 2 (C95985) in the reference to Galibert et al. The Examiner alleges that therein the claimed sequence is taught.

The disclosure of Galibert et al. encompasses the composite

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genome of *Sinorhizobium meliloti*. The claimed biopolymer marker SEQ ID NO:1 is a part of this genome.

Claim 1, as instantly presented, recites specific markers (SEQ ID NOS:1 and 2). Furthermore, since "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03), the scope of the instant claim now encompasses only these two specific peptides (SEQ ID NOS:1 and 2) thus excluding the disclosure of Galibert et al. No where does Galibert et al. specifically teach the claimed biopolymer marker sequence (SEQ ID NO:1). Nor does Galibert et al. teach any peptide which is indicative of a link to Type II diabetes.

Accordingly, Applicants respectfully submit that the claim, as instantly presented, now distinguishes over the sequences taught by Galibert et al. and respectfully request that this rejection under 35 USC 102(a) be withdrawn.

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CONCLUSION

In light of the foregoing remarks and amendments to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,


Ferris H. Lander
Registration # 43,377

McHale & Slavin, P.A.
2855 PGA Boulevard
Palm Beach Gardens, FL 33410
(561) 625-6575 (Voice)
(561) 625-6572 (Fax)
\N\2\SERVER\CLIENT FILES\2100-2199\2132 -Syn-X\2132_000107 - Apolipoprotein Biopolymer
Marker\Amendments\2132_107_AM2.wpd